GEI-067

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: : S. Qazi
MARLANQUETIN et al :
Serial No.: 284,147 : Group: 1616
Filed: April 7, 1999 :
For: HORMONAL...COMPOUND :

600 Third Avenue
New York N.Y. 10016

August 4, 2000

BRIEF ON APPEAL

Asst. Commissioner for Patents
Washington, D.C. 20231

Sir:

REAL PARTY IN INTEREST

The real party in interest is Laboratoire Theramex, a French corporation by way of an assignment from the inventor which assignment has been recorded in the Patent Office.

RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to Appellant, Appellant's legal representative, or Assignee which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

STATUS OF THE CLAIMS

The claims in the application are claims 22 to 34, all other claims having been cancelled.

STATUS OF THE AMENDMENTS

The Rule 116 amendment of May 8, 2000 has been entered for purposes of appeal.

SUMMARY OF THE INVENTION

The present invention has for its purpose to realize the replacement treatment for menopause which cures the climacteric symptomology and prevents osteoporosis and the onset of illnesses which does not create artificial cycles with withdrawal bleeding which is effected by orally administering to said women for 21 to 25 days per month an estrogenic compound and a progestogenic compound of nomegestrol acetate given in combination.

THE PRIOR ART

Lanquetin et al	5,891,867	April 1999
Fraser et al, Medline, AN 89,261,206		March 1989

Volume 11 (1), pp. 2134.

The Lanquetin et al patent is directed to a method for treating estrogen deficiencies in menopausal women by oral administration of an estrogen alone followed by an estrogen-progesterone combination and then a placebo.

The Fraser et al reference relates to the effects of the addition of nomegestrol acetate to post-menopausal estrogen therapy wherein estradiol is orally administered to women who took nomegestrol acetate by the implant administration method at regular intervals for 12 days and the women show a regular progesterone induced withdrawal bleeding each month.

THE ISSUES

All of the claims stand rejected under 35 USC 103 as being obvious over the Fraser et al reference or the Lanquetin et al patent. The Examiner states that the Fraser et al reference teaches the effects of addition of nomegestrol acetate to post-menopausal women and teaches the addition of progesterone to the estrogen to prevent endometrial abnormalities. The Lanquetin et al patent is cited to show treating estrogen deficiencies in menopausal women by the oral administration of an estrogen alone followed by the combination of estrogen-progesterone and then a placebo. The Examiner states that the present invention is broader than the prior art by claiming the simultaneous administration of estrogen and progestative compounds for estrogenic deficiencies and deems that one skilled in art would have been motivated by prepare additional beneficial composition and method for the treatment of estrogenic deficiencies during menopause.

GROUPING OF THE CLAIMS

The claims stand or fall together.

APPLICANTS' ARGUMENTS

Applicants respectfully request the Board of Patent Appeals and Interferences to reverse the Examiner's rejections since the references cited by the Examiner in no way render obvious Applicants' invention or the advantages thereof. As noted above, Applicants' invention relates to a replacement treatment for menopause which cures the symptomology while preventing osteoporosis and the onset of illnesses without withdrawal bleeding and this is in no way taught by the references cited by the Examiner.

The Fraser et al reference relates to the effects of the addition of nomegestrol acetate to menopausal estrogen therapy wherein estradiol is orally administered to women who took nomegestrol acetate by the implant administration method at regular intervals for 12 days. The women in the test showed a regular progesterone induced withdrawal bleeding each month and this in no way teaches Applicants' claimed method of orally administering for 21 to 25 days per month both progesterone and estrogen which prevents the appearance of withdrawal bleeding while avoiding osteoporosis. This is in no way taught by the Fraser et al

reference and it is not even deemed related thereto.

With respect to the Lanquetin et al patent, it is related to a method of treating estrogen deficiencies and establishing an endometrial cycle in menopausal women by orally administering to menopausal women in three different sequences, first an estrogen alone followed by an estrogen progesterone combination and then a placebo over the duration of one month. This has absolutely nothing to do with Applicants' invention which is not a sequential method using estrogen alone and a placebo at certain stages of the month. In contrast thereto, Applicants administered for a continuous 21 to 25 days a combination of estrogen and progesterone and this is in no way even hinted at by the reference.

Therefore, it is deemed that neither reference is even remotely related to Applicants' invention and the Board of Patent Appeals and Interference is respectfully requested to reverse the Examiner's rejections.

CONCLUSION

It is believed that Applicants have complied with all of the necessary requisites for the granting of Letters Patent and therefore, favorable consideration of the application is requested. Three copies of the appeal brief and a check for $300.00 are enclosed herewith.

Respectfully submitted,
Bierman, Muserlian and Lucas

By: _____
Charles A. Muserlian #19,683
Attorney for Applicants
Tel.# (212) 661-8000

CAM:ds
Enclosures

Our Ref.: GEI-067

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:
LANQUETIN et al
Serial No.: 09/284,147
Filed: April 7, 1999
For: HORMONAL...COMPOUND

Group: 1616

Examiner: A. Qazi

600 Third Avenue
New York, NY 10016
Dated: August 4, 2000

APPENDIX

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

The claims on Appeal are as follows:

22. The method of claim 34 wherein the combination is administered continuously.

23. The method of claim 34 wherein the combination is administered intermittently.

24. The method of claim 34 wherein the estrogen is free or esterified estradiol or equine conjugated estrogens.

25. The method of claim 34 wherein the estrogen is an ester of estradiol.

26. The method of claim 25 wherein the ester of estradiol is

estradiol valerate.

27. The method of claim 34 wherein the estrogenic compound of free or esterified estradiol or an equine conjugated estrogen is administered at a dose ranging from 0.5 to 3 mg per unit dose.

28. The method of claim 27 wherein the free estradiol is administered at a dose of 1.5 mg per unit dose.

29. The method of claim 27 wherein the ester of estradiol is administered at a dose of 2 mg per unit dosage.

30. The method of claim 27 wherein the equine conjugated estrogen is administered at a dose of 0.625 mg per unit dosage.

31. The method of claim 34 wherein the progestative is nomegestrol acetate.

32. The method of claim 34 wherein the nomegestrol acetate is administered at a dose ranging from 1.5 to 3.75 mg per unit dosage.

33. The method of claim 34 wherein the nomegestrol acetate is administered at a dose of 2.5 mg per unit dosage.

34. A method of treating the functional disorders brought about by hypoestrogenism in women and avoiding the appearance of

withdrawal bleeding in post-menopausal women comprising orally administering to said women, from 21 to 25 days per month, simultaneously, an estrogenic compound and a progestogenic compound consisting of nomegestrol acetate given in a combination.